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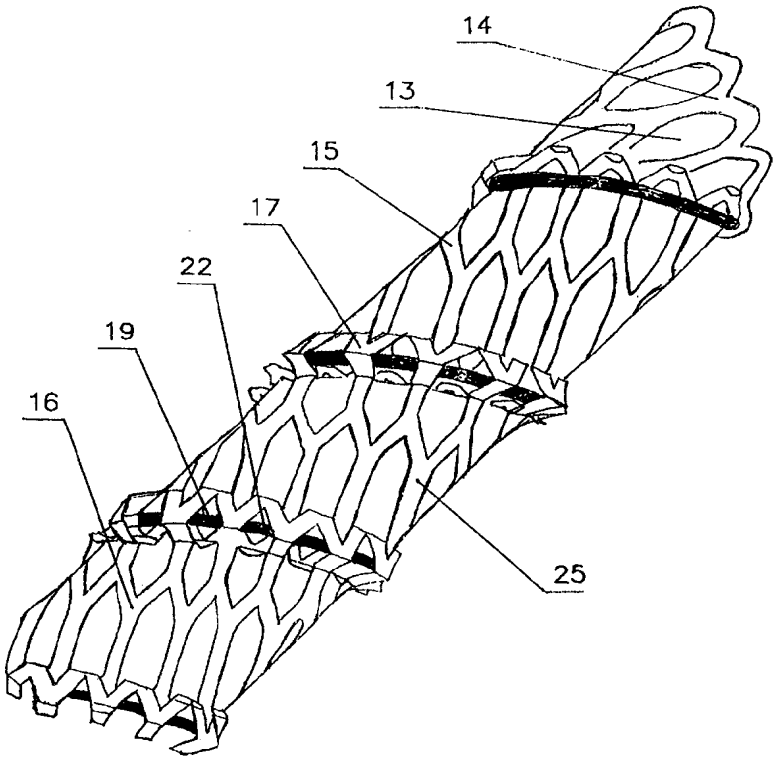
(54) Title: DESIRABLE EXPANDABLE STENT AND TECHNOLOGY OF ITS MANUFACTURING

(57) Abstract

This invention is a thrombo-resistant expandable stent (15) including a coiled tube (16), the tube (16) formed from a thin profiled metallic strip (10) having flanged opposite edges (11, 12) forming a kinematic link (17) with a small hollow bore (18), and the bore (18) accommodating a bio-absorbable local drug delivery constructive element (19). Constructive element (19) can be loaded with regulated concentrations of anti-thrombotic, anti-proliferative or other therapeutic agents for sustained local drug delivery. Upon rolling up of the tube (16) a hollow is marked in a shape of a helical groove along the geometrical axis of the stent (15). Upon expansion of the stent (15) the preliminary geometrical contour (13) of the rigid elements executed on the coiled tube (16) outward surface (21), is transformed into honeycomb cells (24) providing for the development of force according to vessel shape.



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DESIRABLE EXPANDABLE STENT and TECHNOLOGY of its MANUFACTURING

Field and Background of the Invention

The present invention relates to medical technology, particularly to expandable cardiovascular stents, which are intended for the radical arterial lumen recovery with subsequent restoring of the normal blood flow. In the present application the term "stent" refers to the device designed to expand the blood vessel and to maintain the achieved size of lumen. Traditionally, stents are delivered to the target area in the cardiovascular system on the inflatable balloon located on the tip of a transluminal catheter. Then, the balloon is inflated leading to the expansion of the stent thereby widening the lumen of the vessel. Other less common systems for stent delivery also exist.

Most of the existent stents are made from metals. The examples of common designs described in patents are: US 4.733.665, US 4.969.458, US 5.102.417, US 5.195.994, US 5.513.444, WO 91FRO13820. Certain properties of any metallic surface lead to thrombogenicity of the stent once it is implanted within the human cardiovascular system. Therefore, one of the important direction the stent development is the improvement of the stent thromboresistance because this would reduce the need in systematic anticoagulation therapy thereby reducing complication rate after stent implantation. In the present, none of the metallic stents designs have achieved the delicate balance between the desired durability to sufficiently support the vessel wall and flexibility to reduce the thrombogenicity and intimal hyperplasia. Thus, there is a substantial need for anticoagulation and thrombolitic therapy following stent implantation.

Another common flaw of metallic stents is an unequal distribution of forces along the surface of a stent upon its expansion due to the complexity of geometrical shapes of stent's rigid elements. This lead to the unpredictable redistribution of the pressure to the vessel wall with subsequent additional damage to it. In an attempt to overcome this unwanted effect higher pressures are used for the inflation of the balloon which leads to a certain alteration of the stent geometry upon the inflation which affects the shape of the vessel through activation of processes of intimal hyperplasia and thrombosis.

The next substantial disadvantage of existent metallic stent models is the presence of the rigid common element between the longitudinal and diametrical components of a stent. This significantly reduces the flexibility of a stent, limiting its biocompatability with the adjacent vessel wall. This limitation becomes particularly prominent in coronary arteries where blood flow parameters are constantly changing due to their state of continuous motion together with beating heart. As a result of the limited biocompatabi - lity the clinical outcome of stenting worsens. More recent stent designs try to address the above-mentioned flaws by proposing metallic stents, coated with various polymers. Some of these stents include coating, which contains allegedly antiproliferative and antithrombotic drugs to be released locally into the vessel wall.

Another models have bioabsorbable coatings. However, presently used polymers elicit some inflammatory reaction, which narrows the lumen.

Another attempt to widen the clinical applications of stents is lowering the profile of stents and the minimal size of the implanted stent.

Nevertheless, all stents have the lowest diameter of ~ 2 mm upon expansion due to limitations of the existent manufacturing technology. The latter, based mainly on laser technology, remains "the Achilles heel" of stenting due to its high cost, and resulting

in the relatively rough surface of the stent leading to the vessel wall damage.

In summary, the "ideal" stent should possess the following high quality properties: flexibility, trackability, low profile, visibility in the X-ray, thromboresistance, biocompatability, reliable expandability, wide range of available sizes, optional capability of the local drug delivery, and biodegradable coating (see, P.Ruygrok and P.Serruys Intracoronary stenting. "Circulation". 1996; 94; 882-890). These features will widen clinical applications of stenting, enable the reduction of unwanted effects, and ultimately improve the clinical outcome.

The Prior Art

The most effective technical solution for the slotted tube stents, combining both flexibility and radial durability is proposed in the patent application PCT/IL 96/00148 filed on 12.11.1996.

In the above mentioned invention the constructive element, which provides the radial strength of the stent, is constructed in a form of a series of circular bands (2, Fig. 1), disposed over a common longitudinal axis with a number of curvilinear components (3), which plays a role of compensators of the diametrical deformation (CDDs). CDD comprises of at least two rods (4), conjugated in the apex (5) by a V-shaped connection. The loose ends of the rods (4) are closed by the undeformable segments (6) of the circular bands (2).

Upon the expansion of the stent (1), resulting from the outward forces from the inflating balloon, CDDs enable the increase of the diameter of each circular bands (2) up to a certain predetermined size where the degree of the diameter increase is proportional to the number of the CDDs. The maximal diameter of the circular band (2) corresponds to the inner diameter of the vessel wall, and the circular band (2) in this position takes

shape of almost ideal circle with width of one CDD rod. The number of circular bands varies from 2 to 40 depending on the length of the stent.

The longitudinal flexibility of the stent is based on the separation of the static and dynamic functions between the circular bands (2) and the constructive elements of flexibility (7) of the stent, which connect the CDDs. Where the circular band (2) with CDD performs only static function of preventing the vessel wall from collapsing, the constructive element of flexibility (7) of interconnecting zone possesses the significant dynamic function as well, because it needs to reflect the differences in the various segments of the vessel. On another hand, the latter element (7) does not transfer the deformation to the circular bands (2). Therefore, it plays a role of the compensator of the longitudinal deformation (CLD).

CLD (7) comprises of two rods (8), conjugated at the apex (9) by V-shaped 90 degree oriented connection. All the rods (8) have the same length and their loose ends are closed by the undeformable segments (6) of the circular bands (2). The degree of flexibility of the stent depends on the sum of lengths of all CLD rods. Therefore, the optimal positioning of the CLDs between CDDs during manufacturing becomes very important to achieve the maximum possible number of CLDs on each stent.

Fig. 2 shows that upon the expansion of the stent only CDDs change their geometrical forms, whereas CLDs, connected to the undeformable segments (6), do not receive the deformation force from the expansion. On another hand, since all junctions (4) of the CDDs have the same size, the stent maintains the cylindrical shape after the expansion.

The discussed invention also describes the effective approach to increase the longitudinal flexibility of a stent to match the changes of the shape of the pulsating

vessel. This can be accomplished by producing CLDs from the bioabsorbable polymer material. However, that patent application does not describe any particular engineering solution to this idea, probably, because the described model is a slotted tube stent, which almost excludes the possibility of incorporating biodegradable materials.

Another limitation of the slotted tube stent design comes from certain short-comings of manufacturing process, which is most of cases is a laser technology. Particularly, this technology limits the accuracy of the length of CDD rods, the radius of the curve in the V-shaped structures, and the optimal position of the CDDs and CLDs in the original shape of the stent. This may potentially lead upon the expansion of the stent in the moving vessel to the deformation of the stent with subsequent activation of the processes of intimal hyperplasia and thrombosis.

Taking into consideration that the discussed model of the stent is the closest one the "ideal" stent among slotted tube stents, this design nevertheless contains some unresolved flaws, which need to addressed to improve the clinical outcome and minimize such unwanted effects of stenting as thrombosis and restenosis. Therefore, the future "ideal", or desirable expandable stent must possess the following characteristics:

1. Maximal radial strength.
2. Correspondence with the shape of the vessel.
3. Compliance to the pulsating vessel.
4. Low profile.
5. Accommodation of additional angioplasty.
6. Visibility in X-rays.
7. Capability of local drug delivery.
8. Low manufacturing costs with a high quality easily reproducible manufacturing

technology, thus meeting the modern requirements of a cost-effective medical device.

Summary of the Invention

The present invention consists of a stent design with improved thromboresistant properties, which alleviates the need for systematic anticoagulation therapy, and thereby also reduces bleeding and vascular complications.

This aim is achieved by the fact that the Desirable Expandable Stent is made as a coiled tube with the possibility of changing in space the geometrical axis form.

The coiled tube is rolled up from a thin profiled strip in such a way that the flanged opposite edges of the said strip sides form a kinematic link with a small hollow bore, the shape and geometrical sizes of which are preliminary regulated.

On the outward surface of the said coiled tube a plurality of rigid elements in a shape of honeycomb cells is formed. Upon the expansion of the stent, the transformation of preliminary geometrical contour of the rigid elements into the honeycomb cell along the said coiled tube surface occurs corresponding to a vessel shape with the even distribution of the applied force along the stent perimeter, while the radial supporting ability of the stent becomes maximal.

Upon the rolling up of the said coiled tube in the said kinematic link a geometric hollow in a shape of a helical groove deployed on the inner surface along the said stent geometrical axis.

The said stent is provided with a bioabsorbable constructive element, which could be loaded with antithrombotic or antiproliferative agents in regulated concentration for sustained local delivery. The said bioabsorbable local drug delivery constructive element is accommodated in the small hollow bore of the said kinematic link upon the rolling up of the coiled tube.

In the beating heart, in each of the systole-diastole dynamic cycle the flanged opposite edges of the said kinematic link are drifting in the small hollow bore against each other. This facilitates the longitudinal compliance of the said stent body and allows to exert a mechanical influence of the said flanged opposite edges on the said bioabsorbable local drug delivery constructive element accommodated in the small hollow bore. In the said stent the exterior part of the said kinematic link is made over the said coiled tube's outward surface generating line. It makes possible for the said kinematic link's projected exterior part to locally integrate into the vessel wall upon the expansion of the stent.

Before the expansion, the said stent has a diameter, which corresponds to the one of the non-inflated balloon placed on the tip of the catheter. In this case the width of the preliminary contour of the said rigid elements is a function of the vessel inner surface diameter.

The said stent is visible in X-rays due to the corresponding marks made on the surface of the said bioabsorbable local drug delivery constructive element.

Technological process of the said stent's manufacturing includes the following operations:

- cold plastic stamping of rigid elements with preliminary geometric contour on the outward surface of a thin metallic strip;
- profiling a shaped cross-section of a flanged opposite edges on the sides of the said metallic strip with the simultaneous smoothing of metal surpluses on its outward surface after the cold plastic stamping operation;
- rolling up of a coiled tube from the said profiled metallic strip with a simultaneous accommodation of a bioabsorbable local drug delivery constructive element in a small

hollow bore of a formed kinematic link of the said coiled tube;

- fixing of a first end face surface of the said coiled tube and a first end of the said bioabsorbable local drug delivery constructive element;

- separation of the ready device;

- fixing a second end face surface of the said coiled tube and a second end of the bioabsorbable local drug delivery constructive element.

It is possible to manufacture the said stent in an automatic cycle of the said technological operations.

The proposed Desirable Expandable Stent possesses the following characteristics:

1. Maximal radial supporting ability.

2. The unique transformation of the stent geometrical design according to the concept of the uniform force development corresponding to the vessel shape with the guaranteed even distribution of the applied force along the stent perimeter.

3. Compliance to the pulsating vessel.

4. Low profile.

5. Accommodation of additional angioplasty.

6. Visibility in X-rays.

7. Capability of bioabsorbable local drug delivery.

8. Manufacturing of the samples with a diameter from 2.0 to 5.5 mm.

9. Manufacturing of the samples with a length from 10 to 80 mm.

10. Manufacturing of the devices with a highly productive industrial technology, meeting the modern requirements of the automated serial production.

11. High surface purity and quality of the devices.

12. Low manufacturing costs.

The proposed stent design represents medical device executed by joining metallic, scaffolding, and bioabsorbable, therapeutic, parts with a possibility for each of these parts to fulfill an independent functional load.

The proposed stent design possesses a complex of the desirable thromboresistant properties, and therefore, more fully meets the requirements of interventional cardiology. The proposed stent design allows using in practice the scientific achievements on the effective healing of the traumatized vessel wall after angioplasty.

The proposed stent design could be executed taking into account the essential improvement of technological and quality level of the manufactured device, meeting the market requirements, i.e. reduction of the device cost.

Brief Description of the Drawings

The invention is herein described with the help of an example and references to the accompanying drawings, wherein:

Fig. 1 shows the stent-prototype design before the expansion.

Fig. 2 shows the stent-prototype design after the expansion.

Fig. 3 shows the profiled metallic strip with the stamped rigid elements' preliminary geometrical contour along its the outward surface.

Fig. 4 shows the shape of the cross-section of the profiled metallic strip in accordance with Fig. 3.

Fig. 5 shows the rigid element' preliminary geometrical contour as hexahedrons of an irregular shape, which form the profiled metallic strip width in accordance with Fig. 3. Where b - the width of the irregularly shaped hexahedrons.

Fig. 6 shows the proposed stent design before expansion.

Fig. 7 shows the kinematic link cross-section before the expansion of the stent.

Fig. 8 shows the proposed stent design after the expansion.

Fig. 9 shows the kinematic link cross-section after the expansion of the stent.

Fig. 10 shows the honeycomb-shaped rigid elements on the outward surface of the coiled tube after the expansion. Where B - the width of the uniformly shaped hexahedrons.

Specific Description

Fig. 3 shows a thin metallic strip (10) with a shaped flanged opposite edges (11) and (12), which are diametrically curved and are 90 degree oriented on the sides.

Fig. 4 shows a cross-section of the said strip.

Outward surface rigid element' geometrical contour is stamped on the profiled metallic strip (10), forming irregularly shaped hexahedrons (13). On the shown example (fig. 5) the strip's width is formed by two hexahedrons (13), located in a staggered order along the length of the strip (10).

Upon the rolling up of the coiled tube, the end surface (14) are being fixed and cut off, while preserving the integrity of the hexahedrons' outward geometrical contour.

On Fig. 6 and 7 the stent 15 is shown before the expansion and is made up of the profiled metallic strip (10) in a form of a coiled tube (16).

The coiled tube, being an elastic helical spring, has a high longitudinal compliance to the deformation force and upon the curve can change the geometrical axis form.

Upon the rolling up of the coiled tube (16), the flanged opposite edges (11 and 12) of the profiled metallic strip (10) sides form the kinematic link (17) with small hollow bore (18). The kinematic link (17) and the hollow bore dimensions can be specifically calculated to allow one or several bioabsorbable local drug delivery constructive element (19) be located in it, while at the same time the flanged opposite edges (11 and 12), that form the kinematic link (17), could shift against each other upon the bending

force action. This is predetermined by way of changing the metallic strip's (10) geometrical sizes and shapes (Fig. 4) before performing the technological operation of profiling.

The exterior part (20) of kinematic link (17) is made on the outward surface (21) of the generating line of the coiled tube (16). The constructive element (19) of bioabsorbable drug delivery (Fig. 6,7), accommodated in the kinematic link's small hollow bore (18), is made of the polymer thread, which could be loaded with antithrombotic, antiproliferative, or other therapeutic agents in high concentration for sustained local delivery into the vessel wall. On the outward surface of the polymer thread (19) the marks (22) are made, which are visible in X-rays. Upon the rolling up of the coiled tube (16) in the kinematic link (17) a geometrical hollow in a a form of the helical groove (23) is marked (Fig. 7), which is located on the inner surface along the geometrical axis of the stent (15).

The stent diameter before the expansion is determined taking into account the requirement of its dense planting on the non-inflated balloon. The assembly corresponding of the stent and non-inflated balloon is established by the following simple formulas:

$$d = bn/\pi \qquad \text{and} \qquad D = Bn/\pi ,$$

where d - stent diameter before the expansion; D - stent diameter after the expansion, corresponding to the diameter of the inner vessel surface; b - width of the irregular shape hexahedron (Fig. 5, 13); B - width of the regular shape hexahedron (Fig. 10, 24); n - number of the hexahedrons (13) or (24) in a coil (25) of the coiled tube (16).

Fig. 8 and 9 shows the stent (15), which is expanded in the vessel according to the commonly accepted method used in the balloon expandable stents.

It could be seen that the transformation of the rigid elements' geometrical contour takes

place upon the inflation of the balloon. Now on the outward surface (21) of the stent (15) the regularly shaped hexahedrons or honeycomb cells (Fig. 10, 24), which are the unique natural rigid structures, are formed from the irregularly shaped hexahedrons (13).

At the same time the transformation of the rigid elements' preliminary geometrical contour into the honeycomb on the outward surface (21) of the stent (15) is performed according to the design, containing the concept of the uniform development of the force corresponding to the vessel shape.

If the outward force is applied to any point of the expandable stent outward surface (21) it is evenly distributed along the honeycomb cells (24), perimeter in accordance with the known principles of mechanics, then parted along the perimeters of the contiguous honeycomb cells and further along the uniform cellular design of the stent body. Therefore, the stent, after the expansion and with the honeycomb cells (24) formed on its outward surface (21), possesses the maximal radial supporting ability.

The possibility of obtaining relatively small cells decreases the chance of tissue prolapse and plaque protrusion into the lumen. These smaller units account also for a higher radial resistance and decreased wall trauma by decreasing the local pressure on the vessel wall. Since the transformation of the rigid elements' preliminary contour into honeycomb cells (24) is executed from the hexahedrons (13), the stent does not need to use high pressures for the expansion of the balloon.

Upon the expansion of the stent, the exterior part part (20) of the kinematic link (17), made over the generating line of the stent outward surface (21), is introduced into the vessel wall, thus performing an additional angioplasty. Since the elevation of the exterior part of the kinematic link (20) over the generating line of the stent outward surface (21) has a sufficiently small value, the insignificant concentration of stresses

caused by the applied force action could be neglected. At the same time, the presence of the exterior part (20) of the kinematic link (17), that interrupts continuity of the stent outward surface (21) and its helical development along the geometrical axis, increases the maneuverability of the transluminal catheter and facilitates the placement of the stent precisely into the site.

In the beating heart the flanged opposite edges (11 and 12) can shift against each other in the small hollow bore (18) of the kinematic link (17). This facilitates the general longitudinal compliance of the stent body.

The kinematical structure of the coiled tube (16) is determined by the closed coils (25), which have no rigid mechanical connection between them, and, therefore, upon the applied deformation force are able to change the radius of the curve of the stent. Upon the bending of the stent, the contiguous coils (25) curve and, in addition, shift longitudinally in the small hollow bore (18) of the kinematic link (17) against each other in such a way, that the radius of the curve along the stent's outward surface (21) exceeds radius of the curve along its inner surface. At the same time, the difference in the values of the compared radii of the curve corresponds to the tortuous anatomy of diseased vessel. As a result, the stent bends and changes the form of the geometrical axis in accordance with the spatial displacements of the pulsating vessel.

Thus, the proposed stent design , possessing the combination of flexibility and radial strength factor, is executed according to such kinematic scheme, where the stent does not shrink radially upon the applied force and, at the same time, preserves the natural curve of the vessel. Also, the force, which is evenly distributed along the stent perimeter, and decreased local pressure at its ends substantially reduce the possibility of restenosis, while the correspondence to the curvilinear shape of the vessel and the close fitting

against the vessel wall make it possible to perform stenting of complicated long segments and to decrease turbulence.

Besides, in every systole-diastole dynamic cycle of the beating heart the flanged opposite edges (11 and 12) in the kinematic link's small hollow bore (18) have the possibility to mechanically influence the polymer thread (19). This can help the point distribution and the gradual unloading of therapeutic fragments from the polymer thread (19) to the lumen vessel.

When the small hollow bore (18) of the kinematic link (17) is packed with the polymer thread (19), the flexibility of the stent (15) does not change, and the junction made of the flanged opposite edges (11 and 12) in the small hollow bore (18) of the kinematic link (17) works as the elastic hinge. In this case the polymer thread places in the vessel wall and does not nave any functional constructive load and is implanted exclusively for the local drug delivery into the traumatized sections of the vessel.

The marks (22), which are located on the polymer thread (19) and are visible in X-rays on the stent body, increase the efficiency of the interventional procedure since the physician can easily visualize the stent.

The technology of manufacturing of the proposed stent design is a sum of already developed industrial operations, the sequence of which is described in the Summary of the Invention. The mentioned technological processes can be executed within the one assembly unit with high design productivity. The operation of profiling of the flanged opposite edges on the metallic strip sides is being done by simultaneously smoothing of the metallic strip outward surface, which is a positive factor for the improvement in the surface quality and, consequently, in stent functioning. Besides, there is a possibility of manufacturing the preliminary geometrical contour of rigid

elements on the surface of the thin metallic strip, using one of the conventional methods of Photo-Chemical Machining.

In accordance with clinical requirement, the rolling up of the coiled tube from the shaped metallic strip can be done together with simultaneous deployment of one or several bioabsorbable local drug delivery constructive element in the small hollow bore of the kinematic link, that will stimulate improvement in drug therapy of the vessel.

The possibility of creating universal equipment is assumed, where any established stent diameter standard size from 2.0 to 5.5 mm could be manufactured from the same metallic strip blank. On the contrary, the aggregate equipment can be a specialized one.

Thus, the proposed stent design possesses a set of improved thromboresistant properties and could be considered more desirable for the wide clinical practice.

The proposed stent design, being a sum of the accumulated scientific and experimental knowledge, can result in an essential improvement in the coronary interventions due to its features, including the possibility of local drug delivery for different clinical purposes. The proposed stent design also makes it possible to satisfy the needs of the great number of patients undergoing coronary stenting due to the possibility of producing a wide variety of relatively inexpensive medical devices.

The proposed stent design could also be manufactured and used without the introduction of the bioabsorbable local drug delivery constructive element. In this case the stent design preserves all the positive properties of the Optimum Expandable Stent Mechanical Model (slotted tube, wire), and still exceeds it in a number of other important technical and clinical characteristics.

Industrial Applicability

The offered desirable expandable stent is a basis for design, production and application

of a wide spectrum of cardiovascular samples. The stent is recommended for bulk serial and massive production. A preferred mode of the desirable expandable stent production is described above. Still, the construction equivalent element can be improved without losing the invention advantages, formulated as follows.

CLAIMS:

1. Desirable Expandable Stent for insertion a lumen of in a vessel of a living being, comprising:

a) a coiled tube, executed with the possibility to change the geometrical axis form, the coiled tube rolled up from the thin profiled metallic strip in such a way, that the flanged opposite edges of the said profiled metallic strip form a kinematic link with a small hollow bore, the shape and geometrical sizes of which are predetermined;

b) rigid elements formed in a shape of honeycomb cells on the said coiled tube outward surface, whereas upon the expansion of the stent, the transformation of the preliminary geometrical contour of the said rigid elements into the honeycomb cell on the outward surface of the said coiled tube is done according to the concept of the uniform force distribution according to a vessel shape with an even distribution of the applied force along the perimeter of the said stent, and the said stent radial supporting ability becomes maximal;

c) a geometrical hollow in a shape of a helical groove is marked in the said kinematic link from the side of the said coiled tube inner surface and located along the said geometrical axis;

d) a constructive element of bioabsorbable local drug delivery, loaded with antithrombotic, antiproliferative or other therapeutic agents in regulated concentration for sustained local delivery, and accommodated in the small hollow bore of the said kinematic link.

2. Desirable Expandable Stent, wherein every systole-diastole of the beating heart the said flanged opposite edges in the said kinematic link's small hollow bore have the possibility of relative shifting, thus facilitating longitudinal compliance of the said

stent body and mechanically influence by the said flanged opposite edges on the said bioabsorbable local drug delivery constructive element, accommodated in the said kinematic link's small hollow bore.

3. Desirable Expandable Stent, wherein, upon the expansion of the said stent, an exterior part of the kinematic link is executed over the said coiled tube outward surface generating line, thus supporting the local introduction of the said exterior part of the said kinematic link into the vessel wall.

4. Desirable Expandable Stent, wherein the diameter of the said stent before the expansion is executed taking into account its dense fitting on the non-inflated balloon of the transluminal catheter, whereas the width of the rigid element' preliminary geometrical contour is being established proportionally to the inner surface diameter of the vessel.

5. Desirable Expandable Stent as claim 1, wherein the said constructive element of bioabsorbable local drug delivery contains marks that are visible in X-rays of the said stent body.

6. Desirable Expandable Stent, technological process of manufacturing of which includes the following steps:

- cold plastic stamping of the rigid elements' preliminary geometrical contour on the outward surface of the thin metallic strip;
- profiling of a shaped cross-section of a flanged opposite edges on the sides of the said metallic strip with a simultaneous smoothing of metal surpluses on its outward surface after the cold plastic stamping operation;
- rolling up of a coiled tube from the profiled metallic strip with a simultaneous accommodation of a bioabsorbable local drug delivery constructive element in a small

hollow bore of a formed kinematic link of a said coiled tube;

- fixing of a first face surface of the said coiled tube and a first end of the said bioabsorbable local drug delivery constructive element;

- separation of the ready device;

- fixing of a second end face surface of the said coiled tube and a second end of the said bioabsorbable local drug delivery constructive element.

7. Desirable Expandable Stent as in claim 6, wherein is executed in an automatic cycle of the said technological operations.

AMENDED CLAIMS

[received by the International Bureau on 18 November 1998 (18.11.98);
original claim 1b amended; remaining claims unchanged (3 pages)]

1. Desirable Expandable Stent for insertion a lumen of a vessel of a living being, comprising:

a) a coiled tube, executed with the possibility to change in space the geometrical axis form, the coiled tube rolled up from the thin profiled metallic strip in such a way that the flanged opposite edges of the said profiled metallic strip sides form a kinematic link with a small hollow bore , the shape and geometrical sizes of which are preliminary regulated;

b) plurality of the rigid elements formed in a shape of meshy structure on the said coiled tube outward surface, each cell of which is locked by the sides contour of different degree curvature, whereas upon the expansion of the stent, the transformation of the preliminary geometrical contour of the said rigid elements into a final geometrical shape on the said coiled tube outward surface is done according to force scheme of the design uniform development according to a vessel shape with an even distribution of the applied force along the perimeter of the said stent, and the said stent radial supporting ability becomes maximal;

c) a geometrical hollow in a shape of a helical groove is marked in the said kinematic link from the side of the said coiled tube inner surface and located along the said geometrical axis;

d) a constructive element of bioabsorbable local drug delivery loaded with antithrombotic or antiproliferative agents in reglamented concentration for sustained local delivery and accommodated in the said kinematic link small hollow bore.

2. Desirable Expandable Stent as in claim 1, wherein every sistole-diastole

dynamic cycle of the beating heart the said flanged opposite edges in the said kinematic link small hollow bore have the possibility of relative shifting, facilitating the longitudinal compliance of the said stent body and mechanically influencing by the said flanged opposite edges on the said bioabsorbable local drug delivery constructive element, accommodated in the said kinematic link small hollow bore.

3. Desirable Expandable Stent as in claims 1, 2, wherein upon the expansion of the said stent a exterior part of the kinematic link is executed over the said coiled tube outward surface generating line thus supporting the local introduction of the said kinematic link exterior part into the vessel wall.

4. Desirable Expandable Stent as in claims 1, 2, 3, wherein the diameter of the said stent before expansion is executed taking into account the dense fitting on the transluminal catheter non-inflated balloon, whereas the width of the rigid elements preliminary geometrical contour being established proportionally to the inner surface diameter of the vessel.

5. Desirable Expandable Stent as in claims 1, 2 , 3, 4, wherein the said constructive element of bioabsorbable local drug delivery is supplied by marks that are visible in X-rays on the said stent body.

6. Desirable Expandable Stent as in claims 1, 2, 3, 4, 5, ready device of which is done in an automatic cycle of the following technological operations:

- cold plastic stamping of the rigid elements preliminary geometrical contour along outward surface of a thin metallic strip;
- profiling of a shaped cross-section of a flanged opposite edges on the sides of the said metallic strip with a simultaneous smoothing of metal surplusses and

hardening on its outward surface after the cold plastic stamping operation;

- rolling up of a coiled tube from the profiled metallic strip with a simultaneous accommodation of a bioabsorbable local drug delivery constructive element in a small hollow bore of a formed kinematic link of the said coiled tube;

- fixing of a first face surface of the said coiled tube and a first end of the said bioabsorbable local drug delivery constructive element;

- ready device sections;

- fixing of a second end face surface of the said coiled tube and a second end of the said bioabsorbable local drug delivery constructive element.

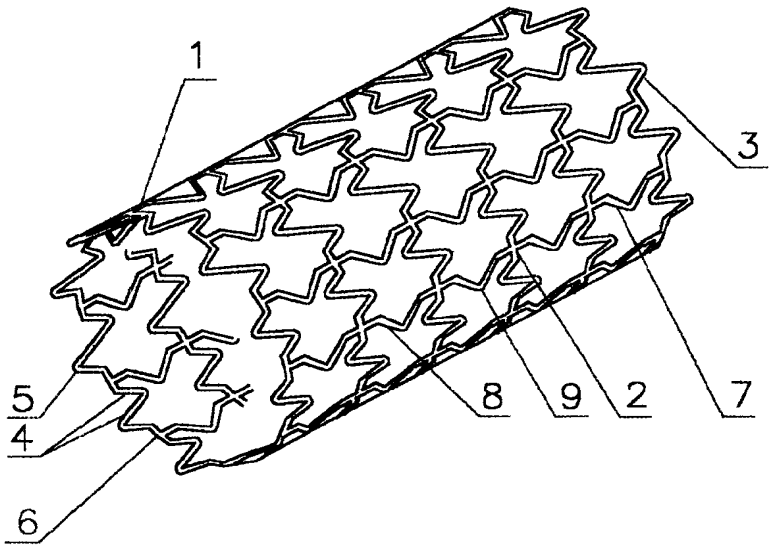

Fig.1

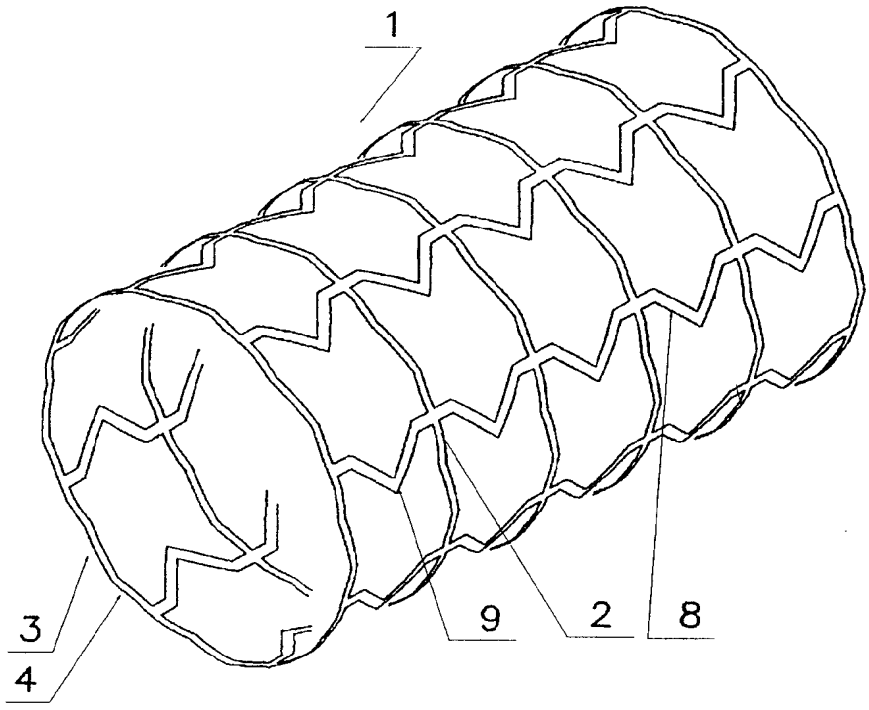

Fig.2

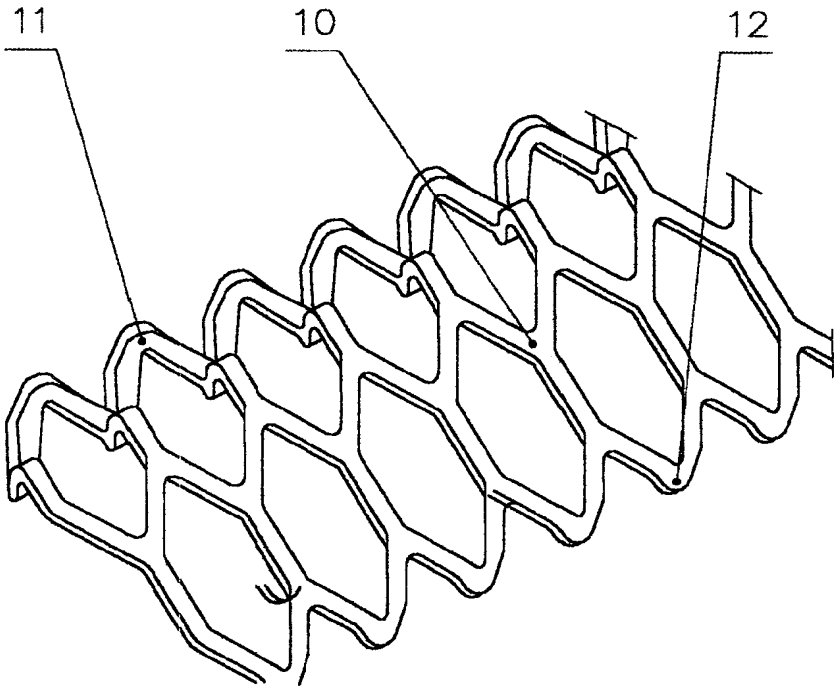

Fig. 3

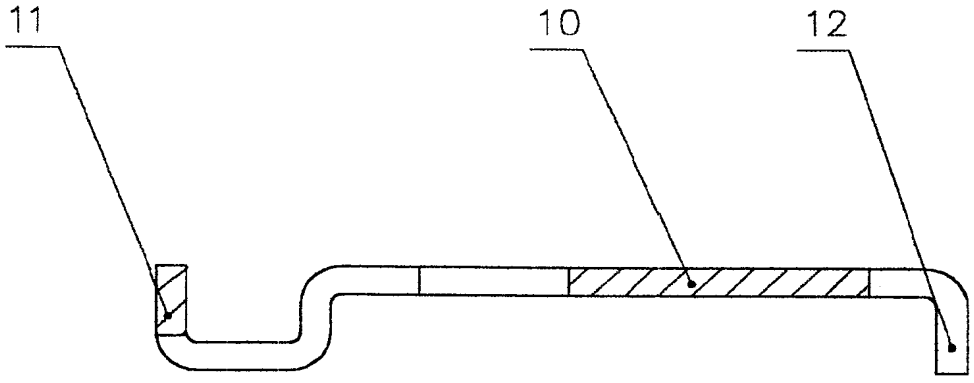

Fig. 4

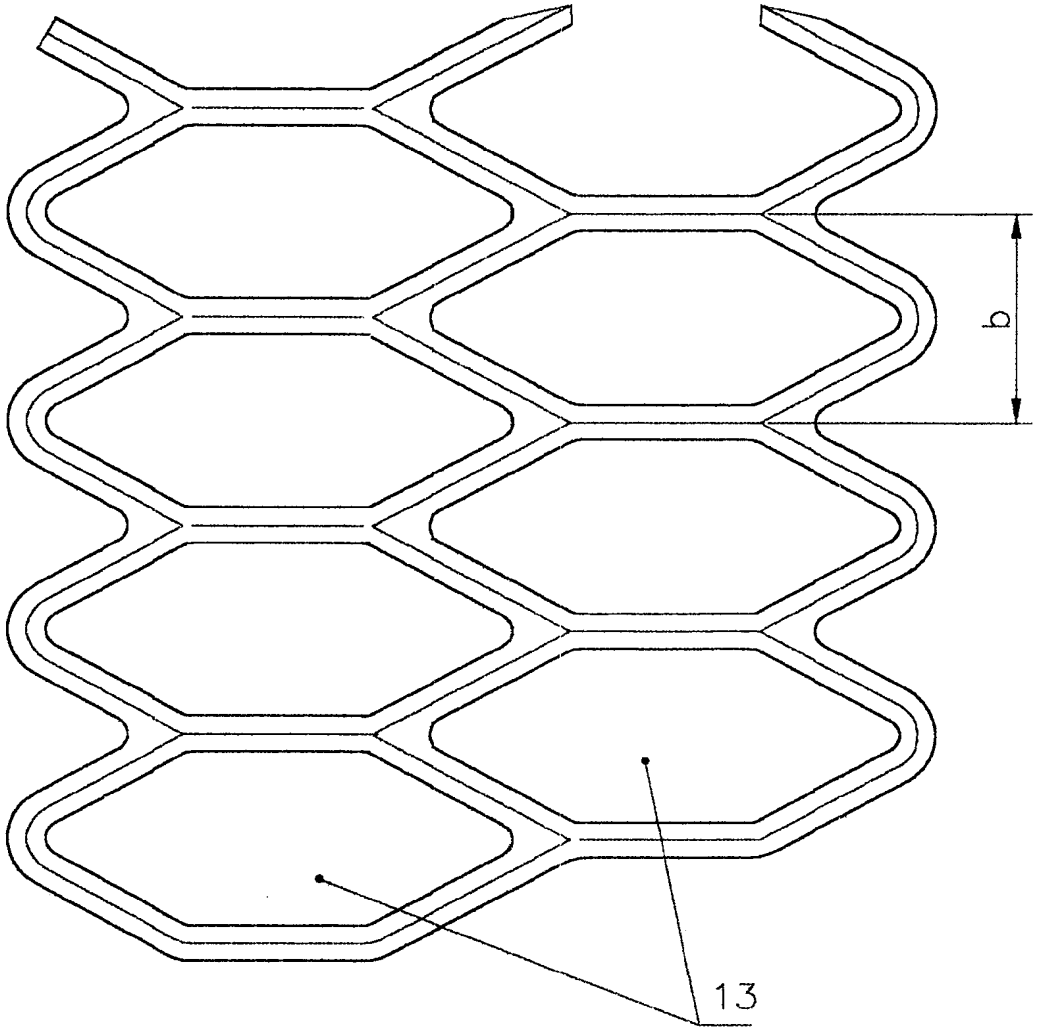

Fig. 5

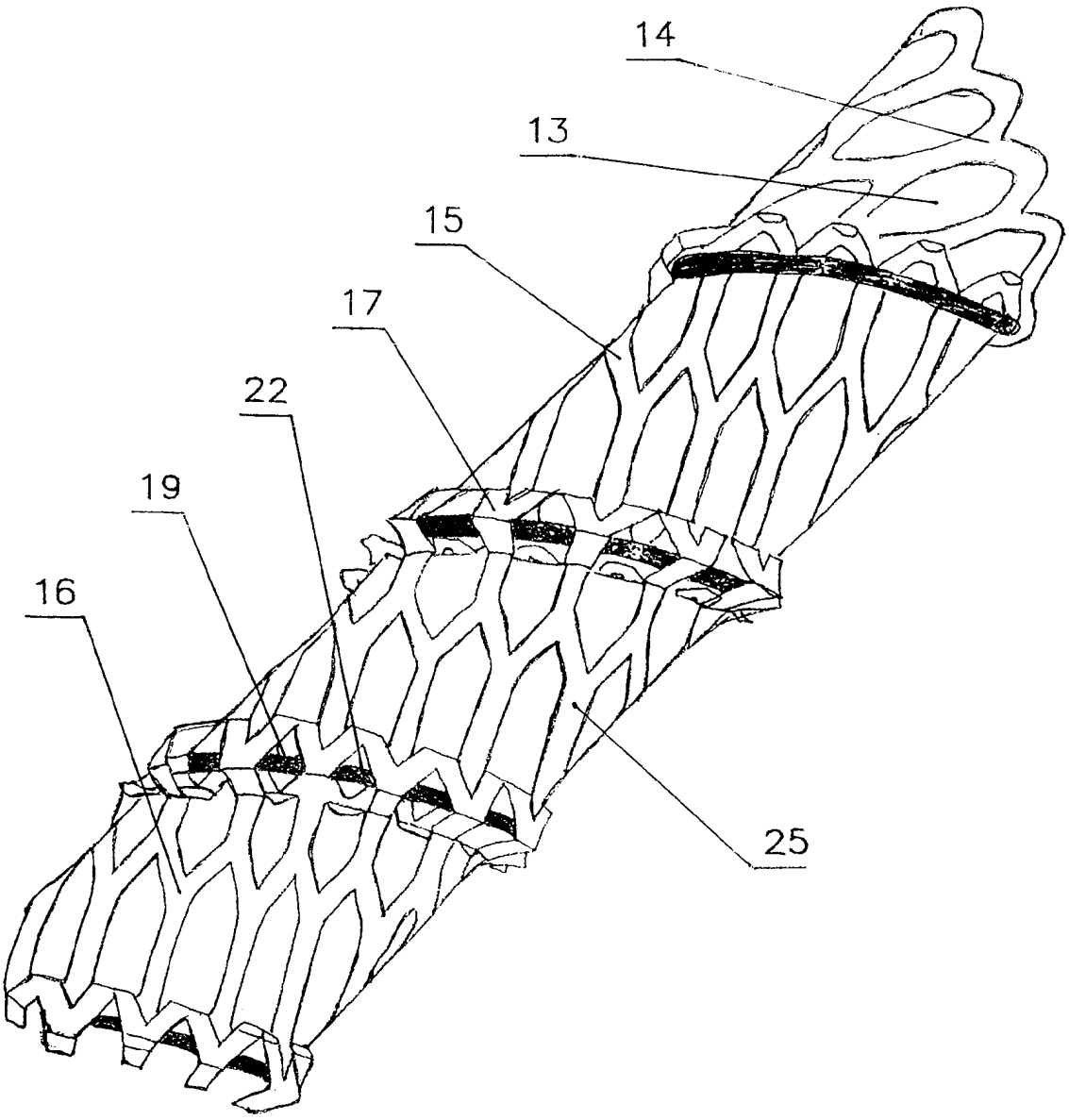

Fig.6

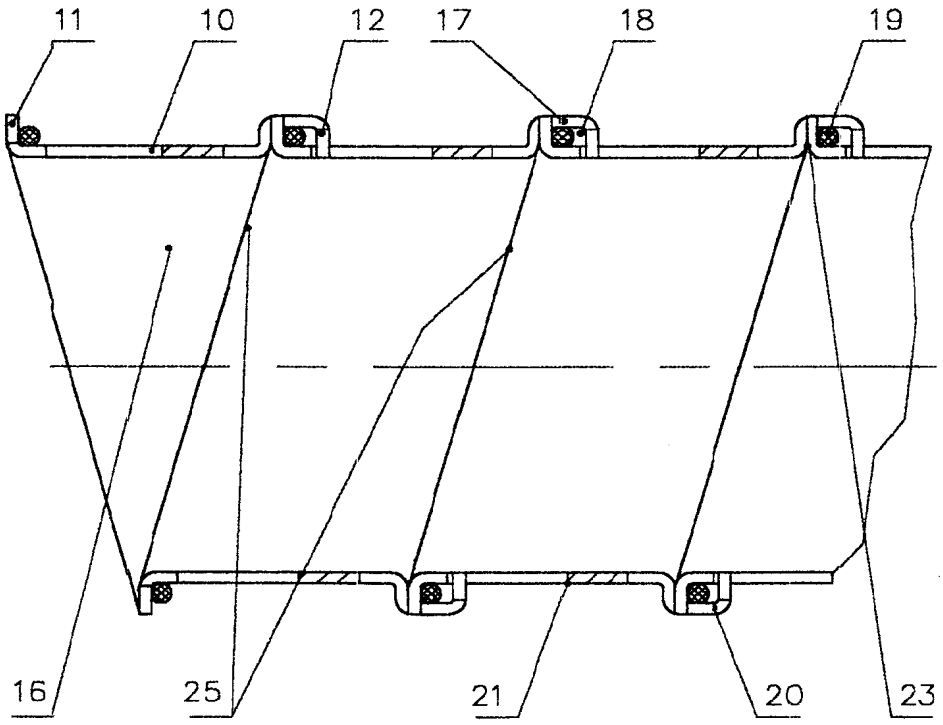

Fig. 7

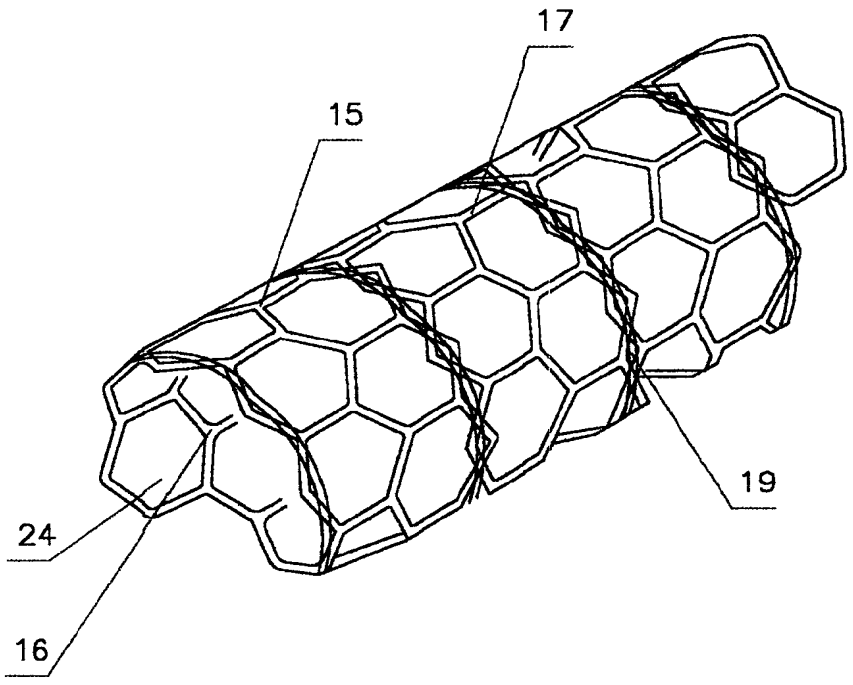

Fig.8

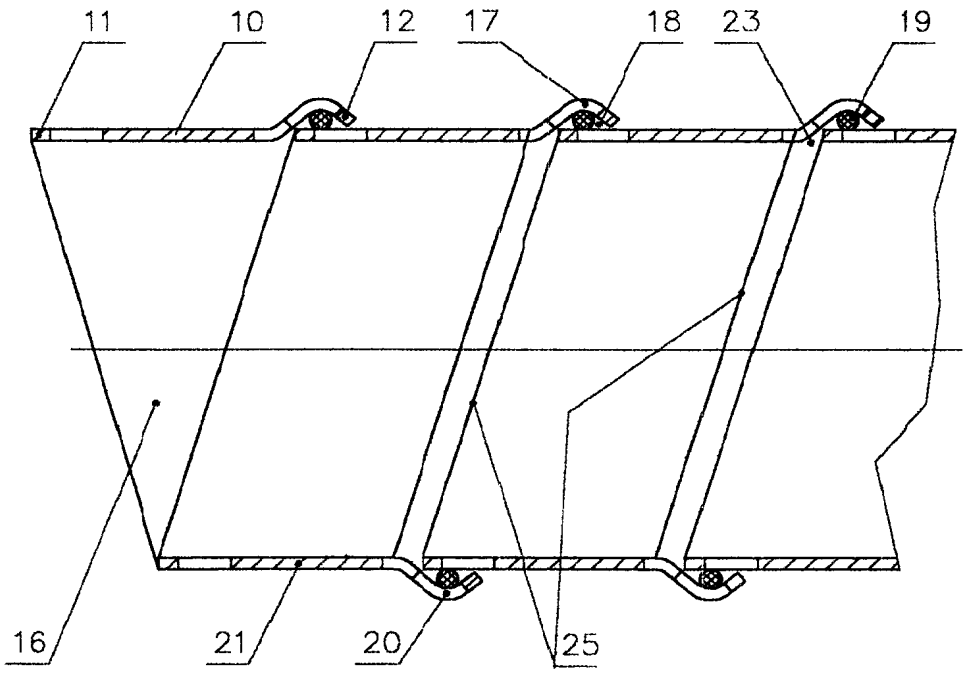

Fig. 9

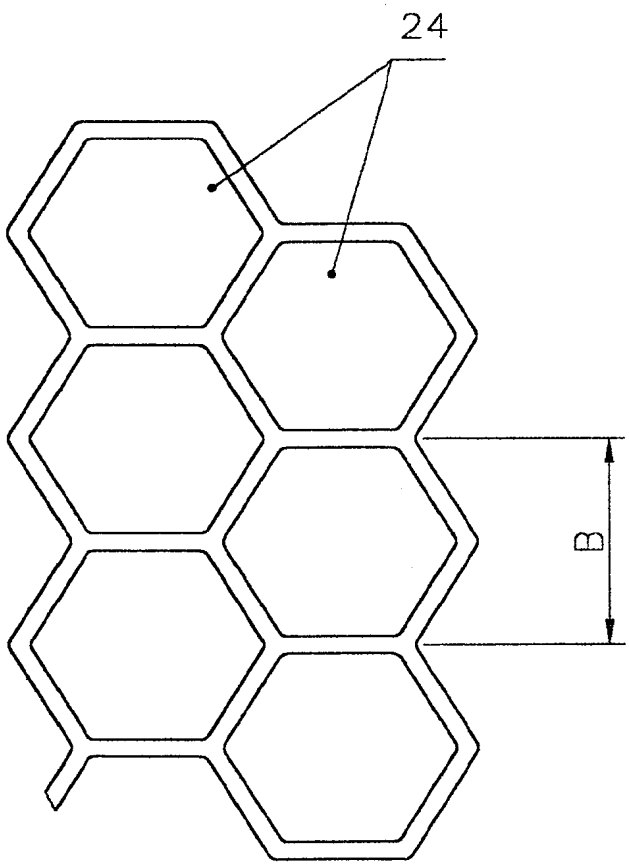

Fig.10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL98/00160

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61F 2/06
US CL : 623.1

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/104; 606/151-158, 191-200; 623/1, 11, 12, 66, 901

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,500,013 A (BUSCEMI ET AL) 19 MARCH 1996, COL. 4 LINE 8 THROUGH COL. 13 LINE 51; AND FIGS. 1-8.	1-7
Y	US 5,578,075 A (DAYTON) 26 NOVEMBER 1996, COL. 5 LINE 45 THROUGH COL. 8 LINE 46; AND FIGS. 1-14.	1-7
Y	US 5,667,523 A (BYNON ET AL) 16 SEPTEMBER 1997, COL. 6 LINE 65 THROUGH COL. 14 LINE 67; AND FIGS. 1-19.	1-7
Y,P	US 5,681,345 A (EUTENEUER) 28 OCTOBER 1997, COL. 5 LINE 61 THROUGH COL. 8 LINE 17; AND FIGS. 1-27.	1-7

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 05 AUGUST 1998	Date of mailing of the international search report 29 SEP 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer FRANK CUDDIHY Telephone No. (703) 308-2996

Form PCT/ISA/210 (second sheet)(July 1992)★

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL98/00160

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,632,771 A (BOATMAN et al) 27 May 1997, col. 4 line 48 through col. 9 line 62; and Figs. 1-21.	1-7
A	US 4,969,896 A (SHORS) 13 November 1990, col. 3 line 16 through col. 5 line 15; and Figs. 1-7.	1-7
Y	US 5,500,013 A (BUSCEMI et al) 19 March 1996, col. 4, line 8 through col. 13, line 51; and Figs. 1-8.	1-7